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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/014,096	02/04/1993	JAMES S. HUSTON	CRP-008DV(20	9218
26161	7590	05/23/2005	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			ULM, JOHN D	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/014,096

Applicant(s)

HUSTON ET AL.

Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-53, 56-61 and 63-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-49, 51-53, 56-59 and 63-68 is/are rejected.
- 7) ☒ Claim(s) 50 and 69 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1) Claims 47 to 53, 56 to 61 and 63 to 69 are pending in the instant application. Claims 47 and 64 have been amended as requested by Applicant in correspondence filed 11 January 2005.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 50 and 69 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5) Claims 47 to 49, 51 to 53, 56 to 59 and 63 to 68 stand rejected under 35 U.S.C. 102(e) as being anticipated by the Cousens et al. patent (4,751,180) in view of Löfdahl et al. (WO 84/03103, 16 Aug. 1984) and Lehninger (Biochemistry, 1978, Worth Publishing, pages 130-131) for those reasons of record in section 5 of Paper Number 31.

In Applicant's previous response to this rejection, Applicant argued that the rejection was in error on two points. First, Applicant argued that the rejection was in conflict with the decision in *In re Wertheim and Mishkin*, 209 USPQ 554 (CCPA 1981). This basis of traversal has been answered at length on the record.

Applicant's second point of traversal was on the premise that "Applicants point out that the two amino acids cannot be part of the cleavage site itself or of the leader sequence, each of which is recited as a separate claim element from the hinge region

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that contains the two required amino acids". In responding to this second point, the Examiner merely pointed out that Applicant was arguing a limitation that was not present in the claims. At no point did the previous office action indicate that such a limitation was distinguishing. To the contrary, the KRSTS and KRSTSTS linkers that were described on page 15 of the Cousens et al. patent application (06/717209) upon which the Cousens et al. Patent is based, each contain a proteolytic cleavage site (-K-R-, a.k.a. -lysine-arginine-) outside of the hinge region (-S-T-S-), and which was not part of the "leader sequence". The fact that the K-R site was intended to be a cleavage site is evidenced by the text in lines 19 to 21 on page 5 of that application, which states that "one may use various proteases" to cleave the fused protein product, "where a series of basic amino acids, such as lysine and arginine act as a cleavage site". Therefore, those limitations newly added to claims 47 and 64 do not distinguish the claimed subject matter from the prior art of record.

6) Claims 60 and 61 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Cousens et al. patent (4,741,180) in view of Löfdahl et al. (WO 84/03103, 16 Aug. 1984) and Lehninger (Biochemistry, 1978, Worth Publishing, pages 130-131) as applied to claims 47 to 49, 51 to 53, 56 to 59 and 63 to 68 above, and further in view of the Cohen et al. patent (4,743,679) for those reasons of record in section 6 of Paper Number 31.

7) Applicant's arguments filed 11 January of 2005 have been fully considered but they are not persuasive.

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8) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

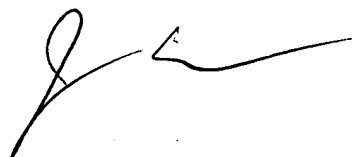
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM
PRIMARY EXAMINER
GROUP 1800